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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,402	ERIKA ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12 and 17-67* is/are pending in the application.

4a) Of the above claim(s) *17-20 and 32-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,21-31 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-10 and 13-16 are cancelled. Claim 67 is added. Claims 17-20 and 32-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/18/2007. Claims 11-12, 21-31 and 67 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Applicant's arguments with respect to claims 11-12 and 21-31 have been considered but are moot in view of the new ground(s) of rejection.

4. Claims 11-12, 21-22, 30-31 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde.,[1] in view of Zanone et al.[2]

The claims are directed to a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance that is an antacid that act protectively through the mucous membrane. Claim 12, which depends on claim 11, requires the gastric acid reducing substance to increase the pH in the stomach to

[1] Vande-Velde, U.S. PreGrant Patent No. 20040013695.

between pH 4 and pH 7. Claims 21-22, which depend on claims 11-12, respectively, require antigenically active substance to be one or more natural antigens, synthetic antigens, antigen mimotopes or a combination thereof. Claims 30-31, which depend on claims 11-12, limit the antigenically active substance be a tumor antigen.

It is noted that Applicant's specification identifies sucralfate and carbenoxolone as antacids act protectively through the mucous membrane.

Vande-Velde teaches a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance. [Abstract, in particular.] The gastric acid reducing agent used by Vande-Velde is an antacid. The antigenically active substances that Vande-Velde teaches include natural and synthetic antigens and tumor antigens. [Claims, page 12, in particular.]

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would

[2] Zanone et al. U.S. Patent No. 6497859, filed 11/17/2000.

have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

Regarding the limitation of claims 12, which requires the gastric acid reducing substance to increase the pH in the stomach to between pH 4 and pH 7, it should be noted that the vaccine composition of Vande-Velde does comprise at least one antacid. The purpose of antacid is to reduce stomach acid level. In view of the known properties of antacids, the vaccine composition of Vande-Velde would have inherently reduced stomach/gastric acid levels, when administered. Hence, while Vande-Velde may be silent on the pH level in the stomach of subjects receiving his vaccine composition, the composition of Vande-Velde does comprise an antacid. Therefore, his vaccine composition would necessarily increase the pH level in the stomach of subjects receiving the vaccine composition. Additionally, Vande-Velde et al. teaches the use of large volumes of antacids to neutralize stomach acids to avoid antigenic degeneration caused by stomach acid. [Paragraphs 002 and 0006, in particular.]

5. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde and Zanone et al., as applied to claims 11-12 and 21-22, in view of Martin et al.[3]

[3] Martin et al. U.S. PreGrant Patent No: 20030049271, which has priority to U.S. Provisional No. 60/269841.

Claim 23, which depends on claim 21, requires the natural or synthetic antigen be coupled to a carrier. Claims 24-25, which depend on claims 22-23, respectively, require the natural or synthetic antigen be conjugated to a carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. While Vande-Velde does suggest the addition of a carrier with his vaccine composition, it is not readily apparent if Vande-Velde coupled and/or conjugated the natural or synthetic antigen to the carrier. [Paragraph 0035, in particular.]

However, at the time the invention was made, Martin et al. establishes that the coupling and conjugation of antigen to a carrier stimulates the development of a stronger immune response. [Paragraph 0100, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to couple and conjugate antigens to a carrier. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to stimulate the development of a stronger immune response. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because coupling and conjugation are routinely practiced in the art.

6. Claims 23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde and Zanone, as applied to claims 11-12 and 21-22, in view of Kricek et al.[4]

[4] Kricek et al. U.S. Patent No. 6610297.

Claim 23 requires that the antigen mimotope be coupled to a carrier. Claims 26-27, which depend on claims 22-23, require the mimotope be conjugated to a carrier. Claims 28-29, which depend on claims 26-27, require that the mimotope be bounded to the carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. It is not readily apparent if Vande-Velde teaches mimotopes.

However, Kricek et al. teaches mimotopes and its conjugation to a carrier.

Hence, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Vande-Velde and Kricek et al. to yield a vaccine composition comprising an antigenic mimotope conjugated/bounded to a carrier and an antacid. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to avoid the antigenic degeneration of the composition of Kricek by stomach acid of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to vaccine compositions to avoid antigenic degeneration is routinely practiced in the art.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

9. Claims 11-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7348010, which was U.S. Patent Application No. 10/469162 in view of Vande-Velde and Zanone et al.

Claims 11-12 are directed to a vaccine composition comprising an antigen and a gastric reducing substance.

Claim 1 of the patent is directed to a composition comprising an antigen. The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the composition of claim 1. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

10. Claims 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-64 of copending Application No. 10/490920 in view of Vande-Velde and Zanone et al.

Claims 63-64 are directed to a composition comprising an antigen. The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the vaccine composition of claims 63-64. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./